



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

01/06/2000

MEMORANDUM

Subject: D259873  
ACLD-128  
EPA File Symbol 3377-LI

From: Wallace Powell, Biologist *Wallace Powell*  
Product Science Branch 1-6-00  
Antimicrobials Division (7510C)

Thru: Karen P. Hicks, Team Leader *Karen P. Hicks*  
Chemistry/Toxicology Team 1/7/00  
Product Science Branch  
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

To: Velma Noble, Product Manager, Team 31  
Jacquie Campbell, Team Reviewer, Team 31  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

BACKGROUND

The applicant, Albemarle Corporation, has submitted acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary dermal irritation, and dermal sensitization studies – MRID Nos. 449244-05 through 449244-09, respectively. The studies were submitted in support of product registration for ACLD-128, EPA File Symbol 3377-LI. The studies were initially reviewed for Product Science Branch (PSB) by Oak Ridge National Laboratory. The reviews are attached to this memorandum.

The applicant additionally has request a waiver of primary eye irritation data, based on corrosiveness indicated in the submitted primary dermal irritation study.

The active ingredients in the product are as follows:

<u>Active Ingredient</u>	<u>% by weight</u>	<u>EPA code</u>
Didecyl dimethyl ammonium chloride .....	5.755	069149
Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride .....	4.725	069105

### RECOMMENDATION

PSB concurs with the acute Toxicity Categories assigned by the attached study reviews. These Categories are listed in the table below and are applicable to all eight product formulations. The one "Basic" and seven "Alternative" formulations for the product appear substantially similar to each other, based on the submitted Confidential Statements of Formula.

Data Requirement	Means of Support	Acute Toxicity Category
Acute Oral Toxicity	Submitted study, MRID 449244-05	Category III, based on the calculated LD <sub>50</sub>
Acute Dermal Toxicity	Submitted study, MRID 449244-06	Category III, based on the limit test
Acute Inhalation Toxicity	Submitted study, MRID 449244-07	Category II, based on determination of a specific range for the LC <sub>50</sub>
Primary Eye Irritation	Waiver request	Category I, considered corrosive. Data waived, based on evidence of corrosion in submitted skin irritation study
Primary Dermal Irritation	Submitted study, MRID 449244-08	Category I, with evidence of corrosion
Dermal Sensitization	Submitted study, MRID 449244-09	Non-sensitizer

### PRODUCT LABELING

Based on the above acute Toxicity Categories, the precautionary (human hazards) and first-aid statements on the submitted draft label (EPA Received date 09/17/99) are acceptable.



DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**  
(ACLD-128)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (81-1)  
MRID 44924405

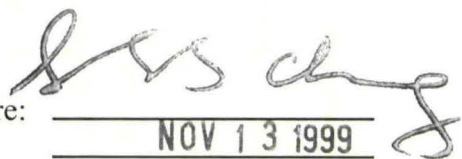
Prepared for

Antimicrobials Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Action No. K129

Primary Reviewer:  
Susan Chang, M.S.

Signature:   
Date: NOV 13 1999

Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: HT Borges  
Date: NOV 13 1999

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross  
Date: NOV 13 1999

Quality Assurance:  
LeeAnn Wilson, M.A.

Signature: L. A. Wilson  
Date: NOV 13 1999

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE

Acute Oral Study (81-1)

EPA Reviewer: Wallace Powell, Ph.D.

 \_\_\_\_\_, Date \_\_\_\_\_

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. \_\_\_\_\_, Date \_\_\_\_\_

**DATA EVALUATION RECORD**

STUDY TYPE: Acute Oral Toxicity - Rat  
OPPTS 870.1100 [§81-1]

DP BARCODE: D259873  
P.C. CODE: 069105

SUBMISSION CODE: S569138  
CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Moore, G.E. (1999) Acute oral toxicity study in rats - Defined LD<sub>50</sub>. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7131, April 7, 1999. MRID 44924405. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44924405) groups of five male and five female fasted young adult Sprague-Dawley derived rats were given a single oral 2000, 2700, or 3500 mg/kg dose of ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) and observed for 14 days.

Three male and five female high-dose rats, three male and two female mid-dose rats, and one male and one female low-dose rats died within five days of treatment. Hunched posture, anogenital staining, hypoactivity, diarrhea, reduced fecal volume, soft feces, and/or distended abdomens were noted from all rats. The survivors recovered by day 7. Some of the decedents had irregular respiration and gasping, were cold to touch, and/or exhibited prone posture prior to death. All surviving rats had normal body weight gains. Moderately red lungs, red/yellow/black intestines, distended/fluid filled/moderately red stomachs, discolored livers, and gaseous distended gastrointestinal tract were noted from the decedents. No gross abnormalities were noted from the survivors.

The oral LD<sub>50</sub>s for males, females, and combined were 2801 mg/kg, 2572 mg/kg, and 2667 mg/kg, respectively.

ACLD-128 is in TOXICITY CATEGORY III based on the LD<sub>50</sub>.

This acute oral study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute oral study (81-1) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test material: ACLD-128

Description: blue liquid

Lot/Batch #: 8504-117

Purity: 10.31% a.i.

Composition: 10.31% Quat

#### 2. Vehicle and/or positive control

None

#### 3. Test animals

Species: rat

Strain: Sprague-Dawley derived

Age and/or weight at dosing: young adult; males: 175-219 g, females: 141-172 g

Source: Ace Animals, Inc., Boyertown, PA

Acclimation period: 6, 8, or 9 days

Diet: Purina Rodent Chow No. 5012

Water: filtered tap water, *ad libitum*

Housing: individually in suspended stainless steel cages with mesh floors

Environmental conditions:

Temperature: 16-26°C

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

#### 1. In life dates

Start: February 4, 17, or 22, 1999; end: March 8, 1999



## 2. Animal assignment and treatment

Following an overnight fast, groups of five rats/sex were given a single 2000, 2700, or 3500 mg/kg dose of the test material by gavage. The animals were observed for clinical signs of toxicity and mortality at least once daily for 14 days. They were weighed on study days 0, 7, and 14. All rats were necropsied.

TABLE 1. Doses, mortality/animals treated			
Dose (mg/kg)	Males	Females	Combined
2000	1/5	1/5	2/10
2700	3/5	2/5	5/10
3500	3/5	5/5	8/10

Data taken from Table 1, p. 11, MRID 44924405.

## 3. Statistics

Calculation of the oral LD<sub>50</sub> was by using Probit Analysis by the method of Finney.

# II. RESULTS AND DISCUSSION

## A. MORTALITY

Mortality is given in Table 1. Three high-dose females died on the day of dosing. One mid-dose male died on day 1. One low-dose female, one mid-dose female, and three males and two females in the high-dose group died on day 2. One low-dose male and one mid-dose female died on day 3. Two mid-dose males died on day 5.

The oral LD<sub>50</sub>s for males, females, and combined were 2801 mg/kg, 2572 mg/kg, and 2667 mg/kg (95% C.L. 2086-3390 mg/kg), respectively. This places ACLD-128 in TOXICITY CATEGORY III.

## B. CLINICAL OBSERVATIONS

Hunched posture, anogenital staining, hypoactivity, diarrhea, reduced fecal volume, soft feces, and/or distended abdomens were noted from all rats. The survivors recovered by day 7. Some of the decedents had irregular respiration and gasping, were cold to touch, and/or exhibited prone posture prior to death.

## C. BODY WEIGHT

All surviving rats had normal body weight gains.

D. NECROPSY

Moderately red lungs, red/yellow/black intestines, distended/fluid filled/moderately red stomachs, discolored livers, and gaseous distended gastrointestinal tracts were noted from the decedents. No gross abnormalities were noted from the survivors.

E. DEFICIENCIES

The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**  
(ACLD-128)

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT (81-2)  
MRID 44924406

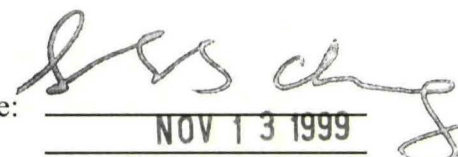
Prepared for

Antimicrobials Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
Arlington, VA 22202


Prepared by

Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
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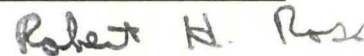
Primary Reviewer:  
Susan Chang, M.S.

Signature:   
Date: NOV 13 1999

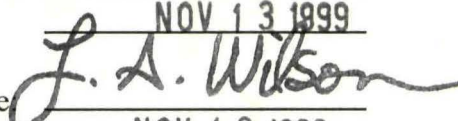
Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature:   
Date: NOV 13 1999

Robert H. Ross, M.S., Group Leader

Signature:   
Date: NOV 13 1999

Quality Assurance:  
LeeAnn Wilson, M.A.

Signature:   
Date: NOV 13 1999

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EPA Reviewer: Wallace Powell, Ph.D.

\_\_\_\_\_, Date \_\_\_\_\_

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. \_\_\_\_\_, Date \_\_\_\_\_

**DATA EVALUATION RECORD**

STUDY TYPE: Acute Dermal Toxicity - Rat  
OPPTS 870.1200 [§81-2]

DP BARCODE: D259873  
P.C. CODE: 069105

SUBMISSION CODE: S569138  
CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Moore, G.E. (1999) Acute dermal toxicity study in rats - Limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7132, April 7, 1999. MRID 44924406. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 44924406) approximately 10% of the body surface area of five male and five female young adult Sprague-Dawley rats was dermally exposed to 2000 mg/kg (Limit Test) ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) for 24 hours. The animals were observed for 14 days.

None of the animals died during the study. One male had anogenital staining on day 1 with recovery by day 2. Blanching and eschar was noted on the dose site of all rats. All rats had normal body weight gains during the study. No gross abnormalities were noted at necropsy.

**The dermal LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg (Limit Test).**

**ACLD-128 is in TOXICITY CATEGORY III based on the LD<sub>50</sub>.**

This acute dermal study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute dermal study (81-2) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test material: ACLD-128

Description: blue liquid

Lot/Batch #: 8504-117

Composition: 10.31% Quat

#### 2. Vehicle and/or positive control

None

#### 3. Test animals

Species: rat

Strain: Sprague-Dawley derived

Age and/or weight at dosing: young adult; males: 214-258 g, females: 193-213 g

Source: Ace Animals, Inc., Boyertown, PA

Acclimation period: 13 days

Diet: Purina Rodent Chow No. 5012

Water: filtered tap water, *ad libitum*

Housing: individually in suspended stainless steel cages with mesh floors

Environmental conditions:

Temperature: 20-22°C

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

#### 1. In life dates

Start: February 1, 1999; end: February 15, 1999

#### 2. Animal assignment and treatment

The study was conducted as a limit test using five male and five female rats. Animals were given a single 2000 mg/kg dose of ACLD-128 applied to a 2x3 inch clipped area (approximately 10% of the body surface). The application site was covered with a gauze pad and wrapped with tape. The covering was removed 24 hours later and the site wiped with water and a towel. The animals were observed for clinical signs of toxicity between one and three hours after treatment and at least daily thereafter for

14 days. They were weighed prior to test material application, and on study days 7 and 14. All rats were sacrificed and necropsied.

3. Statistics

Calculation of the dermal LD<sub>50</sub> was not required.

## II. RESULTS AND DISCUSSION

### A. MORTALITY

None of the rats died during the study.

The dermal LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg. This places ACLD-128 in TOXICITY CATEGORY III.

### B. CLINICAL OBSERVATIONS

One male had anogenital staining on day 1 with recovery by day 2. Blanching and eschar was noted at the dose site of all rats.

### C. BODY WEIGHT

All animals had normal body weight gains.

### D. NECROPSY

No gross abnormalities were noted.

### E. DEFICIENCIES

The humidity and air change frequency of the animal room were not reported. These would not affect the study results.



DATA EVALUATION REPORT

ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE  
(ACLD-128)

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT (81-3)  
MRID 44924407

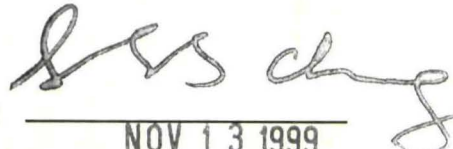
Prepared for

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1921 Jefferson Davis Highway  
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Prepared by

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Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
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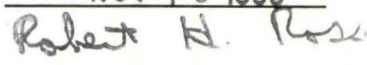
Primary Reviewer:  
Susan Chang, M.S.

Signature:   
Date: NOV 13 1999

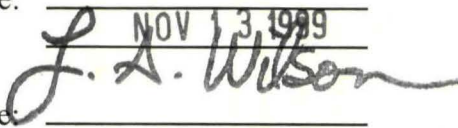
Secondary Reviewers:  
H. Tim Borges, M.T.(A.S.C.P.),  
Ph.D., D.A.B.T.

Signature:   
Date: NOV 13 1999

Robert H. Ross, M.S., Group Leader

Signature:   
Date: NOV 13 1999

Quality Assurance:  
LeeAnn Wilson, M.A.

Signature:   
Date: NOV 13 1999


Disclaimer

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ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE

Acute Inhalation Study (81-3)

EPA Reviewer: Wallace Powell, Ph.D.

 Date \_\_\_\_\_

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. \_\_\_\_\_, Date \_\_\_\_\_

**DATA EVALUATION RECORD**

STUDY TYPE: Acute Inhalation Toxicity - Rat  
OPPTS 870.1300 [§81-3]

DP BARCODE: D259873  
P.C. CODE: 069105

SUBMISSION CODE: S569138  
CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Wnorowski, G. (1999) Acute inhalation toxicity study in rats. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7133, April 6, 1999. MRID 44924407. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 44924407), groups of five male and five female young adult Sprague-Dawley derived rats were exposed whole body to ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) for 4 hours and 15 minutes at a concentration of 0.052 or 0.51 mg/L. The mass median aerodynamic diameters were estimated to be 2.3-2.9  $\mu\text{m}$  and the geometric standard deviations were 1.68-1.75  $\mu\text{m}$ . Approximately 60-76% of particles had an aerodynamic diameter  $\leq 3.3 \mu\text{m}$ . The animals were observed for 14 days.

No rats in the low-dose group died during the study. Eight high-dose rats died during exposure and two high-dose rats died within 15 hours of exposure. Hunched posture, hypoactivity, irregular respiration, and/or dyspnea were noted from all low-dose rats. The rats recovered by day 13 or earlier. In addition, reduced fecal volume was noted from two females in the low-dose group. One male and one female in the high-dose group had irregular respirations, dyspnea, gasping, rales, hunched or prone postures, hypoactivity, and/or red nasal discharges prior to death. With the exception of one male and two females that lost weight during the first week, all surviving rats had normal body weight gains. All decedents had dark, mottled red, extremely edematous lungs. In addition, one female decedent had a discolored liver and one female had slightly red intestines. Two surviving low-dose females had tan, slight gaseous distended intestines. No gross abnormalities were noted from the other survivors.

The  $\text{LC}_{50}$  for males, females, and combined was  $> 0.052 \text{ mg/L}$  and  $< 0.51 \text{ mg/L}$ .



**ACLD-128 is in TOXICITY CATEGORY II based on the LC<sub>50</sub>.**

This acute inhalation study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute inhalation study (81-3) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

**I. MATERIALS AND METHODS****A. MATERIALS****1. Test material: ACLD-128**

Description: blue liquid

Lot/Batch #: 8504-117

Composition: 10.31% Quat

**2. Vehicle and/or positive control**

None

**3. Test animals**

Species: rat

Strain: Sprague-Dawley derived

Age and weight at dosing: young adult; males: 199-239 g, females: 179-214 g

Source: Ace Animals, Inc., Boyertown, PA

Acclimation period: 7 or 9 days

Diet: Purina Rodent Chow No. 5012

Water: filtered tap water, *ad libitum*

Housing: individually in suspended stainless steel cages with mesh floors

Environmental conditions:

Temperature: 17-24°C

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

**B. STUDY DESIGN AND METHODS****1. In life dates**

Start: February 16, 1999; end: March 4, 1999



2. Exposure conditions

Temperature and humidity were recorded every 15 minutes for the first hour of exposure and every 30 minutes thereafter for the remainder of the 4 hour and 15 minute exposure.

3. Animal assignment and treatment

Animals were assigned to the test groups noted in Table 1. Rats were exposed to ACLD-128 by whole body exposure for four hours and 15 minutes. They were observed at least every 30 minutes during exposure, upon removal from chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All rats were necropsied.

TABLE 1. Concentrations, exposure conditions, mortality/animals treated									
Nominal Conc. (mg/L)	Grav. Conc. (mg/L)	MMAD ( $\mu\text{m}$ )	GSD ( $\mu\text{m}$ )	Particles $\leq 3.3 \mu\text{m}$ (%)	Temp. ( $^{\circ}\text{C}$ )	Humidity (%)	Male	Female	Combined
1.22	0.052	2.3-2.4	1.73-1.75	70-76	22	41-52	0/5	0/5	0/10
11.03	0.51	2.9	1.68-1.72	60	21	43-88	5/5	5/5	10/10

Data were taken from pp. 16 and 18-22 and 4 and 6-8, MRID 44924407.

4. Generation of the test atmosphere and description of the chamber

The exposure atmosphere was generated using a 1/4 inch JCO atomizer, FC4 fluid cap and AC1502 air cap (Spraying Systems Inc.). The test material was metered to the atomization nozzle through Tygon tubing using a pump. Filtered air was supplied by an air compressor or compressed dry air connected to the spray atomization nozzle. Additional diluent air was supplied directly to the exposure chamber from filtered conditioned ambient source. The average total airflow was 45.6 liters/min and the whole body exposure chamber volume was 150 L.

Time to equilibrium was approximately 15 min.

Analytical chemistry - None

**Test atmosphere concentration** - Gravimetric samples were collected using glass fiber filters six times from the breathing zone of the animals during exposure. Filter papers were weighed before and after collection to determine the mass collected. The

value was divided by the total volume of air sampled to determine the chamber concentration. The average results are in Table 1 above.

**Particle size determination** - Particle size of each exposure concentration was determined using an eight-stage Andersen cascade impactor. The test material concentration collected by each stage was determined gravimetrically. The aerodynamic mass median diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

#### 5. Statistics

Calculation of the inhalation LC<sub>50</sub> was not required.

## II. RESULTS AND DISCUSSION

### A. MORTALITY

No rats in the low-dose group died during the study. Eight high-dose rats died during exposure and two high-dose rats died within 15 hours of exposure.

The LC<sub>50</sub> for males, females, and combined was > 0.052 mg/L and < 0.51 mg/L. This places ACLD-128 in TOXICITY CATEGORY II.

### B. CLINICAL OBSERVATIONS

Hunched posture, hypoactivity, irregular respirations, and/or dyspnea were noted from all low-dose rats. The rats recovered by day 13 or earlier. In addition, reduced fecal volume was noted from two females in the low-dose group. One male and one female in the high-dose group had irregular respirations, dyspnea, prone posture, gasping, rales, hunched posture, hypoactivity, and/or red nasal discharges prior to death.

### C. BODY WEIGHT

With the exception of one male and two females that lost weight during the first week, all surviving rats had normal body weight gains.

### D. NECROPSY

All decedents had dark, mottled red, extremely edematous lungs. In addition, one female decedent had a discolored liver and one female had slightly red intestines. Two surviving low-dose females had tan, slight gaseous distended intestines. No gross abnormalities were noted from the other survivors.

E. DEFICIENCIES

The humidity and air change frequency of the animal rooms were not reported. These would not affect the study results.



DATA EVALUATION REPORT

**ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE**  
(ACLD-128)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (81-5)  
MRID 44924408

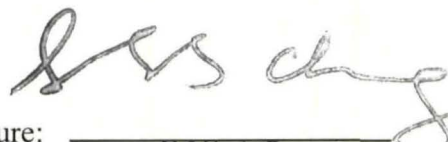
Prepared for

Antimicrobials Division  
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1921 Jefferson Davis Highway  
Arlington, VA 22202


Prepared by

Chemical Hazard Evaluation Group  
Toxicology and Risk Analysis Section  
Life Sciences Division  
Oak Ridge National Laboratory  
Oak Ridge, TN 37831  
Action No. K129


Primary Reviewer:  
Susan Chang, M.S.

  
Signature: \_\_\_\_\_  
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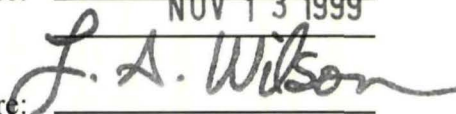
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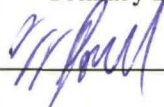
Disclaimer

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ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE

Primary Dermal Irritation Study (81-5)

EPA Reviewer: Wallace Powell, Ph.D.

 \_\_\_\_\_, Date \_\_\_\_\_

EPA Work Assignment Manager: Nader Elkassabany, Ph.D. \_\_\_\_\_, Date \_\_\_\_\_

**DATA EVALUATION RECORD**

STUDY TYPE: Primary Dermal Irritation - Rabbit  
OPPTS 870.2500 [§81-5]

DP BARCODE: D259873  
P.C. CODE: 069105

SUBMISSION CODE: S569138  
CASE NO.: 066315

TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)

SYNONYMS: not reported

CITATION: Moore, G.E. (1999) Primary dermal irritation study in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7135, April 7, 1999. MRID 44924408. Unpublished.

SPONSOR: Albemarle<sup>®</sup> Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44924408) one male and two female adult New Zealand white rabbits were dermally exposed to 0.5 mL ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117) for 4 hours on the dorsal trunk. The animals were observed for 10 days. Irritation was scored by the method of Draize.

Very slight and well defined erythema were noted on 1/3 and 2/3 rabbits, respectively, one hour following patch removal. By 24 hours, well defined to moderate erythema was noted on all rabbits that intensified to severe by 72 hours and persisted through the end of the study. Moderate to severe edema was noted on all rabbits one hour after patch removal that persisted through day 7. By the end of the study, slight to moderate edema was noted on all rabbits. Eschar was present on all rabbits by 72 hours that persisted through the end of the study.

**In this study, ACLD-128 was corrosive and is in TOXICITY CATEGORY I for primary dermal irritation.**

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a primary dermal irritation study (81-5) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.



## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test material: ACLD-128

Description: blue liquid

Lot/Batch #: 8504-117

Composition: 10.31% Quat

#### 2. Vehicle

None

#### 3. Test animals

Species: rabbit

Strain: New Zealand white

Age and weight at dosing: adult; weight of males and females not reported

Source: Davidson's Mill Farm, South Brunswick, NJ

Acclimation period: 13 days

Diet: pelleted Purina Rabbit Chow No. 5326

Water: filtered tap water, *ad libitum*

Housing: individually in suspended stainless steel cages with mesh floors

Environmental conditions:

Temperature: 20-22°C

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

#### 1. In life dates

Start: February 2, 1999; end: February 12, 1999

#### 2. Animal assignment and treatment

One male and two female animals were given a single 0.5 mL dose of ACLD-128 applied to a 6 cm<sup>2</sup> clipped intact site on the dorsal trunk. The application sites were covered with gauze and wrapped with semi-occlusive tape. Elizabethan collars were placed on the rabbits. The dressings were left in place for 4 hours, after which they were removed and the application sites wiped with water and a towel. The sites were scored for erythema and edema according to the Draize method 1, 24, 48, and 72 hours, and 7 and 10 days after patch removal.



## II. RESULTS AND DISCUSSION

- A. Very slight erythema and well defined erythema were noted on 1/3 and 2/3 rabbits, respectively, one hour following patch removal. By 24 hours, well defined to moderate erythema was noted on all rabbits that intensified to severe by 72 hours and persisted through the end of the study. Moderate to severe edema was noted on all rabbits one hour after patch removal that persisted through day 7. By the end of the study, slight to moderate edema was noted on all rabbits. Eschar was present on all rabbits by 72 hours that persisted through the end of the study.

ACLD-128 was corrosive and is in TOXICITY CATEGORY I.

B. DEFICIENCIES

The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

# DATA EVALUATION REPORT

## ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (ACLD-128)

STUDY TYPE: DERMAL SENSITIZATION - GUINEA PIG (81-6)  
MRID 44924409

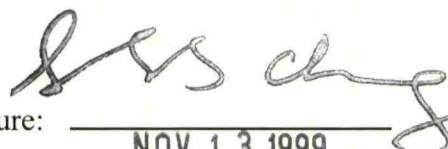
Prepared for

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U.S. Environmental Protection Agency  
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Prepared by

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Action No. K129

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Date: NOV 13 1999

### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Wallace Powell, Ph.D.

\_\_\_\_\_, Date \_\_\_\_\_

EPA Work Assignment Manager: Nader Elkassabany, Ph.D.

\_\_\_\_\_, Date \_\_\_\_\_

<b>DATA EVALUATION RECORD</b>
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STUDY TYPE: Dermal Sensitization - Guinea Pig  
OPPTS 870.2600 [§81-6]

DP BARCODE: D259873SUBMISSION CODE: S569138P.C. CODE: 069105CASE NO.: 066315TEST MATERIAL (PURITY): ACLD-128 (10.31% Quat, a.i.)SYNONYMS: not reported

CITATION: Wnorowski, G. (1999) Dermal sensitization test (Buehler method). Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory project identification number 7136, April 7, 1999. MRID 44924409. Unpublished.

SPONSOR: Albemarle® Corporation, Health & Environment, 451 Florida Street, Baton Rouge, LA 70801-1765

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 44924409) with ACLD-128 (10.31% Quat, a.i., Lot No. 8504-117), 30 young adult male Hartley guinea pigs were tested using the Buehler method.

Very faint to moderate erythema was noted on all animals 24 and 48 hours after the first induction. No to faint usually confluent erythema was noted on all animals 24 and 48 hours after the second induction. No to very faint usually nonconfluent erythema was noted on all animals 24 and 48 hours after the third induction. Following challenge, dermal irritation suggestive of sensitization was not observed on the test or naive control animals after challenge. The study report included a DNCB positive control study which was carried out within six months of the current study. The results were appropriate.

**In this study, ACLD-128 was not a dermal sensitizer.**

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a dermal sensitization study (81-6) in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.



## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test material: ACLD-128

Description: blue liquid

Lot/Batch #: 8504-117

Composition: 10.31% Quat

#### 2. Vehicle and positive control

Vehicle: distilled water; positive control: 1-Chloro-2,4-dinitrobenzene (DNCB)  
(historical data)

#### 3. Test animals

Species: guinea pig

Strain: Hartley

Age and weight at start of treatment: young adult; males: 349-400 g

Source: Davidson's Mill Farm, South Brunswick, NJ

Acclimation period: 6 days

Diet: pelleted Purina Guinea Pig Chow No. 5025

Water: filtered tap water, *ad libitum*

Housing: individually in suspended stainless steel cages with mesh floors

Environmental conditions:

Temperature: 18-23 °C

Humidity: not reported

Air changes: not reported

Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

#### 1. In life dates

Start: January 27, 1999; end: February 25, 1999

#### 2. Animal assignment and treatment

The animals were induced and challenged according to the method of Buehler. The dorsal area and flanks of 30 male guinea pigs were clipped. For the induction phase, 0.4 mL of test material in distilled water was applied with an occlusive 25 mm Hilltop Chamber for six hours once each week for three weeks to the dorsal flank of 20 test animals. The test material was 6%, 6%, and 4% in distilled water for the first, second, and third induction, respectively. Twelve days after the last induction dose, the animals were challenged with 0.4 mL of 2% test material in distilled water under

occlusion to naive sites for 6 hours. A naive control group (10 animals) was treated with 0.4 mL of 2% test material in distilled water at challenge only. Reactions were scored 24 and 48 hours post exposure.

## II. RESULTS AND DISCUSSION

### A. INDUCTION REACTIONS AND DURATION

Very faint usually nonconfluent erythema (score = 0.5), faint usually confluent erythema, and moderate erythema were noted on 8/20, 11/20, and 1/20 animals, respectively, 24 hours after the first induction. Very faint usually nonconfluent erythema, faint usually confluent erythema, and moderate erythema were noted on 9/20, 9/20, and 2/20 animals, respectively, 48 hours after the first induction. No to faint usually confluent erythema was noted on all animals 24 and 48 hours after the second induction. No to very faint usually nonconfluent erythema was noted on all animals 24 and 48 hours after the third induction.

### B. CHALLENGE REACTIONS AND DURATION

Very faint usually nonconfluent erythema was noted on 7/20 test animals 24 hours following challenge with resolution on 3/20 animals by 48 hours. Very faint usually nonconfluent erythema was noted on 4/10 naive control animals 24 hours following challenge with resolution on 1/10 animals by 48 hours.

ACLD-128 was not a dermal sensitizer.

### C. POSITIVE CONTROL

The study report include a DNCB positive control study which was carried out within six months of the current study. The results were appropriate.

### D. ADDITIONAL TESTING

It is the reviewer's opinion that the study was conducted in a manner suitable to detect the sensitization potential of the test material. No additional testing is needed.

### E. DEFICIENCIES

On page 21 in the study report, the table was misidentified as challenge phase skin reaction scores (test substance). This table should be the naive control skin reaction scores after challenge. The humidity and air change frequency of the animal room were not reported. These would not affect the study results.